

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

**I. Status of the Claims**

Claim 27 is requested to be amended. Exemplary support for this amendment can be found in paragraph [0040] of the specification.

Claims 36-40 are requested to be added. Exemplary support for these claims can be found in claims 27-31 and 35 and paragraph [0046] of the specification.

Upon entry of the foregoing amendments, claims 1-31, 35-40 will be pending in this application, and claims 1-26 and 30 are withdrawn. Thus, claims 27-29, 31, and 35-40 will be pending and subject to examination on the merits.

**II. Claim Rejections – 35 U.S.C. § 102**

Claims 27-29 and 31-35 stand rejected as allegedly anticipated by Bhardwaj *et al.*, J. CLIN. INVEST. 98:715-722 (1996) as evidenced by Hackstein *et al.*, BLOOD 100(3):1084-1087 (2002) and Kelleher *et al.* INT'L IMMUNOLOGY 10(6):749-755 (1998). Applicants respectfully traverse this ground of rejection.

Bhardwaj and Kelleher fail to teach or suggest the claimed invention for the reasons discussed in detail in Applicants' response of August 7, 2007. Generally, neither Bhardwaj nor Kelleher teach or suggest a "therapeutic composition," as claimed. Instead, these references generally disclose cell cultures. The references lack any suggestion that the cell cultures can be used for any therapeutic purpose. Moreover, Applicant's submitted a declaration from Dr. Lotze confirming that the cell cultures of Bhardwaj and Kelleher are not physiologically compatible.

The Examiner continues to reject the claims, because "cells in culture are considered to be compatible with physiological conditions and not incompatible with pharmaceutical use." The Examiner

also contends that “the cell culture medium[s] taught by Bhardwaj [and Kelleher are] compatible with physiological conditions.” This position is both factually and legally incorrect.

The broadest reasonable interpretation of claims must be used during examination, but “[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.” MPEP § 2111. This broadest reasonable interpretation is based on the “ordinary and customary meaning” claim terms would have to one of ordinary to skill in the art. 2111.01(II).

Here, one of skill in the art would not consider cell cultures generated for basic research purposes to be “therapeutic compositions.” A “therapeutic composition” is a composition formulated to be administered to a subject for a therapeutic purpose. Cell cultures are maintained under conditions optimal for their particular purpose, such as conditions favoring growth of some particular type of cell. Cell cultures are *not* formulated in such a way as to be administered to a subject, as described in the Lotze Declaration. Thus, “therapeutic composition” cannot be reasonably construed as encompassing Bhardwaj’s and Kelleher’s cell cultures.

The Examiner’s factual position that “the cell culture medium[s] taught by Bhardwaj [and Kelleher are] compatible with physiological conditions” lacks record support. The Lotze Declaration describes in detail why Bhardwaj’s and Kelleher’s cell cultures are not physiologically compatible. The Examiner takes a contrary position but offers no evidence or explanation to support the position. Because the evidence and explanation of record demonstrate that the cell cultures are *not* compatible with physiological positions, Bhardwaj and Kelleher cannot anticipate the claims.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

### CONCLUSION

Applicants believe that the present application is in condition for allowance. Favorable reconsideration is requested, therefore. Also, Examiner Juedes is invited to contact the undersigned directly, should any issue warrant further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required regarding this application under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany the response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extensions of time are needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of any such extensions fees from the deposit account.

Respectfully submitted,

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By 

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